



DIVISION OF CONSOLIDATED LABORATORY SERVICES

PROTOCOL FOR THE
CHEMISTRY CERTIFICATION OF LABORATORIES
PERFORMING DRINKING WATER ANALYSIS
IN THE STATE OF VIRGINIA

1.0 Scope and Application:

- 1.1 This document describes the Division of Consolidated Laboratory Services (DCLS) protocols for the utilization of water supply proficiency testing studies and on-site laboratory assessments to certify, continue certification and re-certify in-state laboratories and out-of-state laboratories participating in the State reciprocal agreement under the provisions of the Safe Drinking Water Act (SDWA).
 - 1.1.1 The laboratory must demonstrate acceptable performance on Proficiency Testing (PT) samples for all certifiable parameters by each method, for which the laboratory seeks certification, at least once a year.
 - 1.1.2 An on-site assessment of the in-state laboratory is to be performed at least once every three years to ensure that the laboratory is using the SDWA methods authorized for the analyses, including quality assurance/quality control practices and documentation that will attest to the verity of those analyses.
- 1.2 The procedures employed by DCLS for the evaluation of laboratories performing drinking water analyses are those detailed in the Manual for the Certification of Laboratories Analyzing Drinking Water, Criteria and Procedures, Quality Assurance, (EPA 815-R-05-004, dated January 2005). This manual is referred to as the “Laboratory Certification Manual” in this standard operating procedure (SOP). In general, the following elements are required of an in-state laboratory and an out-of-state reciprocal laboratory performing analyses for the Safe Drinking Water Act (SDWA) Public Water System Supervision Program.
 - 1.2.1 For each parameter by each method for which the laboratory seeks certification the status may be: “certified” (meets the minimum requirements of the Laboratory Certification Manual); “provisionally certified” (has deficiencies but demonstrates the ability to produce valid data within the accuracy and precision of the test); or “not certified” (major deficiencies which result in unreliable data).
 - 1.2.2 DCLS has, as a principal laboratory in EPA Region Three, major analytical capability and/or enforcement responsibility for water supplies with respect to analytical data under the Safe Drinking Water Act.
 - 1.2.3 EPA Region Three may assist state authorities by conducting on-site assessments of private and municipal laboratories in the State of Virginia under emergency situations, but even in these cases the state authority will have the primary responsibility to issue a state SDWA certification.

2.0 Responsibilities:

- 2.1 The Certification Authority (CA) is the EPA Regional Administrator. The CA has delegated the authority and responsibility for the SDWA drinking water laboratory certification program in the State of Virginia to the Certification Program Manager.
- 2.2 The Certification Program Manager has signature authority for all SDWA laboratory certifications granted by EPA Region Three and is the Director of the DCLS.
- 2.3 The management of Virginia's SDWA PT program is the responsibility of the Certification Officers (CO). There is no PT program for microbiology in the State of Virginia.
- 2.4 The management of the State of Virginia SDWA on-site assessments is the responsibility of the COs for chemistry.

3.0 Procedure for Handling the Results for Chemical Parameters on Water Supply (WS) Proficiency Testing (PT) Studies:

- 3.1 The chemistry PT samples are prepared as concentrates and are available commercially from providers who have been approved by the National Institute of Standards and Technology utilizing the "National Standards for Water Proficiency Testing Studies".
- 3.2 It is the responsibility of the individual laboratories within the State to initiate the purchase and analysis of Water Supply PT samples from NIST certified provider. A PT schedule is included in Appendix A which details the time lines for PT participation by laboratories within the State of Virginia.
 - 3.2.1 The individual laboratories are to instruct the PT providers to submit copies of the results to the CO at DCLS, 600 North 5th Street, Richmond, Va. 23219.
- 3.3 The individual laboratories must participate in WS PT studies during September of each calendar year. During this "primary PT period", the individual laboratories must analyze WS PT samples for all certifiable parameters by each method for which the laboratory seeks certification.
 - 3.3.1 It is the responsibility of the individual laboratories to provide a written corrective action plan to the CO that addresses any "not acceptable" PT results within 30 days of receipt of the report from the PT provider.
 - 3.3.2 Failure to respond according to this protocol, e.g. failure to provide a corrective action plan may result in downgrading the certified laboratory to "not certified" for the unacceptable parameters.

- 3.3.3 The certification status for any failed analytes/methods, for which a corrective action plan is received, will be “provisionally certified”. The certification status for all parameters for which “acceptable” results were reported will be “certified”.
- 3.4 The CO will complete a PT Performance Record Table for each laboratory within the State which participates in the SDWA certification program following the primary PT testing period and will issue PT status update reports by May 1st of each year. This report will indicate the current recommended certification status.
- 3.5 It is the responsibility of the individual laboratories within the State to initiate the purchase and analysis of “make-up” Water Supply PT samples during the first and second quarters (January through May) for those analytes for which “not acceptable” results were reported for the main PT period (September through November of the previous year).
 - 3.5.1 The individual laboratories are to have the PT providers send the results of the make-up PTs to the CO.
 - 3.5.2 Only method analytes which were originally “not acceptable” should be repeated in make-up studies.
 - 3.5.3 It is the individual laboratory’s responsibility to assure that one “acceptable” WS PT result was achieved for all certified chemical parameters by each method for which the laboratory seeks certification by May 30th of each year.
 - 3.5.4 The individual laboratories may participate in as many PTs as necessary during the make-up PT period, but for any parameter for which an acceptable WS PT has not been achieved by May 30th, the certification status is “not certified”. Under this circumstance, the individual laboratories must stop analysis of SDWA compliance samples for this method-analyte and send the samples to a laboratory which is certified to perform such analyses. After May 30th, the PT certification status will remain unchanged until the issuance of the next PT status update report letter.
 - 3.5.5 The CO will complete a PT Performance Record Table for each individual laboratory following the make-up PT testing period and will issue a final PT status update report by June 30th of each year.
- 3.6 The PT records will be maintained by the CO as part of the State SDWA Program files. A separate file for each individual laboratory will be maintained containing the last 5 calendar years of summary letters detailing the laboratory PT certification status (starting with the letters issued in June of each year). The routine cycle (detailed in previous sections) will begin September 1st of each year and will continue after that date.

3.6.1 PT records are filed by laboratory name and year and consist of: PT provider reports for the WS PT studies; PT Status Update Reports and associated PT Performance Record Tables; corrective action reports from the laboratories; and the summary letter from the CA.

3.6.2 The PT Performance Record Table is the principal PT tracking tool to record progress toward achieving full PT certification.

3.7 Given the difficulties encountered with privatization of the PT program and the need to update the PT certification status of all the individual State laboratories in Virginia each year, each individual laboratory is to provide copies of WS PT results which indicate the successful analysis of all parameters per methods for which the laboratory seeks certification by May 1st. By June 30th the CO will issue a PT status update report.

3.8 In June of each year, an overall certification status report will be officially issued by the Certification Authority for the State of Virginia. This will reflect the current certification status (by method and analyte) based upon the laboratory's PT performance and any on-site assessment conducted that year.

4.0 Procedure for all On-Site Assessments of State Laboratories:

4.1 A local State laboratory must participate in an on-site assessment at least once every three years. The date for the inspection will be mutually agreeable to the CO and the laboratory management. Typically assessments will require a one day on-site at the laboratory.

4.2 The laboratory will be "fully certified" by analyte and method if it meets the minimum requirements of the SDWA Laboratory Certification Manual, e.g., follows the required methods and performs the required QC including a MDL and IDC (method specified).

4.2.1 The certification will routinely be valid for up to three years, but may be updated as necessary with the loss of key analyst/s or equipment.

4.3 Pre-survey information is requested prior to an on-site assessment to provide the assessors with the necessary background material to fully prepare for the evaluation. This includes the completion of the Microbiology Laboratory Analysis Review Checklist (from the Laboratory Certification Manual). In addition, the local laboratory is requested to provide copies of the last three PTs prior to the on-site.

4.4 The basic procedures for conducting an on-site assessment are those outlined in the Laboratory Certification Manual (Recommended Protocol for Regions Conducting On-Site Laboratory Evaluations). As part of the assessment, a data audit is performed.

- 4.4.1 The data and calculations are checked for at least two compliance samples (one from the current year and one from a past year) and one PT sample ideally for each method. If time does not permit this approach, then the raw data and calculations are checked for each technology, e.g., gas chromatography, ion chromatography. In addition, the corresponding supporting data for the initial demonstration of performance and method detection limits are reviewed. The local laboratory's Quality Assurance Manual is reviewed as part of this assessment and copies are maintained on file in the CO's office of DCLS.
- 4.5 The assessment team members are SDWA COs who have successfully completed the COs training course provided by the EPA's Office of Ground Water and Drinking Water and necessary laboratory safety training.
 - 4.5.1 The team members have extensive first hand experience with performing analyses and their assessment area is focused to match their bench experience (inorganic non-metals, organic chemistry and metals analyses). A listing of the SDWA COs and their CO training, experience and credentials is at Appendix B.
 - 4.5.2 Newly certified COs accompany an experienced member of the assessment team for three assessments before performing an inspection on their own.
 - 4.5.3 The assessment team generally includes 1-2 members depending on the size and complexity of the laboratory.
- 4.6 The assessors may utilize method specific and general SDWA checklists for the evaluation of local laboratories. The checklists are an aid for the assessors (for their use). Similarly, notes taken while on-site are for the assessor's use.
- 4.7 The closing conference, at which time all findings are discussed, is particularly important in the State of Virginia on-site assessment protocol, since the assessment report is issued as a final report (draft reports are not prepared).
- 4.8 Assessment reports follow the basic outline provided in the Laboratory Certification Manual (Evaluation Report for Principal State Laboratories and Laboratories in Non-Primary States), and include a recommended certification status for each analyte by each method.
 - 4.8.1 The final report is completed within 60 days of the on-site assessment and is issued under cover letter from the Certification Program Manager who is the Director of DCLS.
 - 4.8.2 For local laboratory assessments, "Findings" are defined as factual, objective statements, which provide evidence of non-conformance with any of the following: the Agency's SDWA mandatory methods; official Agency mandates and policies,

e.g., 40 CFR 142.10; CFR holding times and preservation requirements and “deviations” from the Manual for the Certification of Laboratories Analyzing Drinking Water, 5th Edition (2005, U.S. EPA); and documented practices that adversely affect the quality of the data (supported with actual data from case files).

- 4.8.3 The on-site assessment reports also contain “Recommendations”. These are not findings, but are the technical opinions of the auditor that are offered to further improve the laboratory’s quality system (technical exchange). In addition, “General Comments” are included in the report that is a partial listing of innovative or exceptional items the assessment team wanted to highlight (not intended to be an all inclusive listing).
- 4.8.4 Downgrading of certification as a result of an on-site assessment is based upon the technical judgement of the CO concerning the potential impact to the data quality. The rationale for recommendations of downgrading to “provisionally certified” or “not certified” is captured in the conclusion section of the assessment report.
- 4.8.5 General findings (non-critical) may result in the recommendation for downgrading the certification to “provisionally certified”. Such findings should result in the generation of useable data within acceptable quality control limits. However, these findings must be corrected. A “provisionally certified” laboratory may analyze drinking water samples for compliance purposes.
- 4.8.6 Critical findings would necessitate that the CO recommend the downgrading of certification to “not certified” for the corresponding analytical method and analyte. Such findings could result in the generation of unusable data and must be corrected immediately before additional compliance analysis can proceed.
- 4.9 The local laboratory is requested to respond within 60 calendar days with a corrective action plan to address all inspection findings. To assist with document control and speed the process, the corrective action plan is requested both as hardcopy and in an electronic file format.
- 4.10 After review of the corrective action plan, “Update Reports” will be generated for each specialty area (organic chemistry and inorganic chemistry) as appropriate. These reports will provide updates to the recommended certification status in the assessment report, as well as the rationale for any changes, and will be sent to the local laboratory with a copy kept on file at DCLS.
 - 4.10.1 This report will also indicate any additional corrective actions necessary to achieve full certification and may necessitate additional communications and corrective action reports or products. The update reports serve to document the current recommended laboratory certification status based upon the on-site assessment.

- 4.11 Upon completion of all necessary corrective actions, a “Completion Letter” is sent by the CO to the local laboratory.
- 4.12 The CO is to retain the permanent record of on-site assessments. The records (hardcopy and, as possible, in electronic format) are sorted by State and year and include the completed pre-survey package.
 - 4.12.1 The assessment records are to be retained for 6 years (at least two inspections cycles).
 - 4.12.2. The assessment information is also summarized by the CO in a tabular format. This table lists: laboratory; assessment team; dates (final report, corrective action report, up-date reports and completion report).
- 4.13 A local laboratory which does not have certification for required regulated analytes (either through downgrading to “not certified” or due to lack of analytical capability) must have compliance analyses performed by an SDWA certified laboratory. The local laboratory is to provide the CO with information on the commercial laboratory.

5.0 Each year the CO will officially issue an overall certification status report. This will reflect the current certification status (by method and analyte) based upon the laboratory’s PT performance and any on-site assessment conducted that year.

APPENDIX A

WS PT Schedule	PT Report to Provider	PT Report Received at DCLS
September of current year	November of current year	December of current year
March of succeeding year	May of succeeding year	June of succeeding year

APPENDIX B

NAME	EDUCATION	SDWA EXPERIENCE
Eileen Q. Sanders	BS Environmental Health	18 years
R. Tracy Hunter	BS Chemistry	16 years
Theresa Payne	BS Chemistry	6 years
Dawn Luginbuhl	BS Microbiology	5 years